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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Wolfgang Lechner

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EXAMINER

HOPKINS, CHRISTINE D

ART UNIT

PAPER NUMBER

3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,793	Applicant(s) LECHNER, WOLFGANG	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17 and 19-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1, 3, 4, 10-14, 23 and 24 is/are allowed.
- 6) ☒ Claim(s) 2, 5-9, 15, 17 and 22 is/are rejected.
- 7) ☒ Claim(s) 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 August 2008 has been entered. Claims 1-15, 17 and 19-24 are now pending. The Examiner acknowledges the amendments to claims 1, 7, 15, 17, 19 and 20, as well as the cancellation of claims 16, 18 and 25.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2, 5-7, 9, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Baro et al. (U.S. Patent No. 4,399,809). Baro et al. discloses an apparatus to be applied to a stoma within the body, comprised of chambers to be inflated or deflated with a fluid in response to pressure monitored by a sensor. Baro teaches a gastric band **1** having a non-extensible back such that it cannot expand outward upon inflation of the chambers (col. 4, lines 54-57). The band is arranged in

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such a way as to encircle the intestine near the stoma (col. 4, lines 9-13). The band may have two chambers **8**, **9** that communicate with each other via a passage **3** for the introduction and removal of fluid used to inflate and deflate the chambers such that the restriction of the stoma is controlled (col. 4, lines 27-33). The chambers are located beside each other whereby the first chamber may be located aborally (see Fig. 4). With reference to the improvements of claim 2 and claim 5, a second chamber **9** is interpreted as a “sensor” for the detection of pressure since it responds by deflation upon a pressure increase from the stomach in relation to the consumption of food. The first chamber **8** is connected to the second chamber **9** via a passage **3** leading to a conduit **4** which is connected to a pump having a “reservoir chamber” that supports fluid which is supplied to or removed from the chambers to ensure control of restriction (col. 3, lines 49-58 and Fig. 4). Furthermore, the first and second chambers are arranged one above the other with respect to the stomach (see Figs. 1 and 4). Referring to claim 6, a “layer” is provided between the chambers **8** and **9** as evident in Fig 4.

With reference to claims 7 and 9, a mechanical, manually activated pump is provided for pumping a fluid into the chambers. Since a passage **3** exists between the chambers, it is thus capable of distributing fluid from the second chamber into the first chamber and vice versa (col. 3, lines 49-58 and Fig. 4). Regarding claim 15, when a given pressure has been detected by sensing device **12**, decompression of the band is advised by removal of fluid from the first chamber of the band via the pump. Prior to eating and an increase in pressure, the band is in an inflated state, which is a result of supplying fluid from a “reservoir chamber” of a pump to the first chamber. While fluid is

supplied to both chambers, the language of claim 15 only requires supplying liquid to or removing liquid from the first chamber.

Referring to claim 17, a conduit **4** is interpreted as an air chamber arranged between a reservoir supplying fluid through the pump and the first chamber **8** (see Fig. 4).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al. (U.S. Patent No. 4,399,809) in view of Imran et al. (U.S. Patent No. 7,037,343). Baro discloses the invention as claimed, see rejection supra; however Baro fails to teach a pump that is electrically driven. Imran teaches an implantable stomach prosthesis, composed of expandable members, for controlling passage of food from the stomach to the small intestine. With respect to claim 8, Imran discloses a DC powered pump for selectively inflating and deflating expandable members (col. 6, lines 40-50), or the equivalent of inflatable chambers as taught by Baro, from a reservoir. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have utilized an electric pump as suggested by Imran to introduce fluids to, and also remove them from, an inflatable chamber similar to that of Baro, acting to constrict a body lumen.

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6. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baro et al. (U.S. Patent No. 4,399,809) in view of Chen et al. (U.S. Patent No. 5,690,691). Baro discloses the invention as claimed, see rejection supra; however Baro fails to teach a device emitting an electrical pulse for stimulating the stomach. Regarding claim 22, Chen discloses the use of electrodes for controlling the peristaltic wave and therefore stimulating the flow of food through the stomach (col. 3, lines 34-45 and col. 6, lines 43-67-col. 7, lines 1-4). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have incorporated electrodes as suggested by Chen to a chamber sensing pressure of the stomach as taught by Baro such that electrical pulses emitted by the electrodes act to stimulate the stomach during food intake by invoking satiety and stimulating the muscles of the stomach to constrict and further decrease the stoma opening.

Allowable Subject Matter

7. Claims 1, 3, 4, 10-14, 23 and 24 are allowable over the prior art of record. The following is a statement of reasons for the indication of allowable subject matter: In view of claim 1, the prior art fails to teach or suggest: a gastric band including a nonextensible back having a first chamber and second chamber, both arranged on a stoma side of the back, wherein the second chamber communicates with the first chamber by displacement of liquid via an auxiliary chamber, wherein a valve between the second chamber and auxiliary chamber allows transport of liquid only from the second chamber to the auxiliary chamber and a further valve between the auxiliary

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chamber and the first chamber allows transport of the liquid from the auxiliary chamber to the first chamber.

8. Claims 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: Regarding claims 19-21, the prior art of record teaches a pump for facilitating liquid exchange from a reservoir to a chamber, however it fails to teach or suggest: a gastric band including a nonextensible back having a first chamber and second chamber, both arranged on a stoma side of the back, wherein the second chamber is a sensor for detection of a pressure increase in the stomach or esophagus, and the first and second chambers are connected with a reservoir chamber in a manner to control restriction by displacement of liquid between the reservoir chamber and the first chamber, wherein a device for carrying out liquid exchange from the first to the second chamber or reservoir chamber, respectively, is provided between the first and second chamber or reservoir chamber, respectively; wherein the device for liquid exchange is comprised of a common partition wall with micropores arranged between the chambers.

Response to Arguments

9. Applicant's arguments filed 25 August 2008 with respect to the rejection of claims 2, 5-7, 9, 15 and 17 under 35 U.S.C. 102(b) citing Baro ('809) have been fully considered and are not persuasive. Applicant contends that the reservoir chamber of

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claim 2 is part of the controllable gastric band, and is not an external pump as mentioned in Baro. However, this argument is not persuasive. Based on the language of claim 2, it is clear that the first and second chambers are provided on "a stomach or esophagus side of the back" of the band. However, based on the claim language, it does not appear that the "reservoir chamber" is also part of the back itself.

Nonetheless, it is still considered to be a part of the controllable gastric band as argued.

Applicant further contends that the new limitation of a "reservoir *chamber*" clearly distinguishes over the "pump" of Baro. However, this argument is not persuasive.

Since a reservoir can also be defined as a "chamber," it would stand that the inclusion of the term "chamber" as a limitation would not act to further distinguish over the pump of Baro. In view of the foregoing, the rejection of claims 2, 5-7, 9, 15 and 17 under 35 U.S.C. 102(b) citing Baro ('809) has been maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735